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AND G.D. SEARLE LLC

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

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| IN RE BEXTRA AND CELEBREX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION<br>*This document relates to*<br>ALBERTA A. KREITZER,<br>Plaintiff,<br>vs.<br>PFIZER, INC., PHARMACIA CORPORATION, G.D. SEARLE LLC and MONSANTO COMPANY,<br>Defendants. | MDL Docket No. 1699<br>CASE NO. 3:08-cv--02149-CRB<br>**PFIZER INC., PHARMACIA CORPORATION, AND G.D. SEARLE LLC'S ANSWER TO COMPLAINT**<br>**JURY DEMAND ENDORSED HEREIN** |

NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (f/k/a Monsanto Company[1]) ("Pharmacia") and

[1] Plaintiff's Complaint names "Monsanto Company" as a Defendant. Defendants state that in 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and

G.D. Searle LLC ("Searle") (collectively "Defendants") and file this Answer to Plaintiff's Complaint ("Complaint"), and would respectfully show the Court as follows:

## I.
## PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiff was prescribed or used Bextra® (valdecoxib) ("Bextra®"). Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Bextra®.

## II.
## ORIGINAL ANSWER

### Response to Allegations Regarding Parties

1. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

2. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York, and that it is registered to do business in the State of Minnesota. Defendants admit that Pfizer may be served through its registered agent. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Bextra® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are therefore without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

does not and has not ever designed, produced, manufactured, sold, resold, or distributed Bextra®. Given that Plaintiff alleges in the Complaint that Monsanto Company was involved in distributing Bextra®, *see* PLAINTIFF'S COMPLAINT at ¶ 5, Defendants assume Plaintiff means to refer to 1933 Monsanto. As a result, Pharmacia will respond to the allegations directed at Monsanto Company.

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3. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois, and that it is registered to do business in the State of Minnesota. Defendants admit that Searle may be served through its registered agent. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are therefore without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants admit that in 1933 an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever manufactured, marketed, sold, or distributed Bextra®. The 2000 Monsanto is not and has never been the parent of either Searle or Pharmacia. As the 2000 Monsanto does not and has not ever manufactured, marketed, sold, or distributed

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Bextra®, Defendants therefore state that the 2000 Monsanto is not a proper party in this matter. Defendants deny the remaining allegations in this paragraph of the Complaint. Defendants state that the response to this paragraph of the Complaint regarding Monsanto is incorporated by reference into Defendants' responses to each and every paragraph of the Complaint referring to Monsanto and/or Defendants.

6. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants deny the remaining allegations in this paragraph of the Complaint.

7. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

8. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are therefore without

knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

9. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of Minnesota. Defendants deny the remaining allegations in this paragraph of the Complaint.

10. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of Minnesota. Defendants are without knowledge sufficient to form a belief as to the allegations in this paragraph of the Complaint regarding the amount in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiff claims the amount in controversy satisfies the jurisdictional amount of this Court. Defendants deny the remaining allegations in this paragraph of the Complaint.

**Response to Factual Allegations**

11. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

12. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Bextra® caused Plaintiff injury or damages and deny the remaining allegations in this paragraph of the Complaint.

13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with

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applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that, in the ordinary case, Bextra® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

15. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

16. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs ("NSAIDS"). Defendants state that the allegations in this paragraph of the Complaint regarding aspirin, naproxen and ibuprofen are not directed toward Defendants, and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint regarding aspirin, naproxen and ibuprofen. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

17. The allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this

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paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

18. The allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

19. The allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

20. The allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

21. Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

22. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are therefore without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

23. Plaintiff does not allege having used Celebrex® in this Complaint. Nevertheless, Defendants admit that Celebrex® was launched in the United States in February 1999. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants admit that, during certain periods of time,

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Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not directed toward Defendants, and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

24. Defendants admit that the New Drug Application for Bextra® was filed with the FDA on January 15, 2001. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are therefore without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

25. Defendants admit that Bextra® was approved by the FDA on November 16, 2001. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

26. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult

rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

27. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

28. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are therefore without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

29. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that Bextra® was and is safe and effective when used in accordance

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with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

30. The allegations in this paragraph of the Complaint are not directed towards Defendants, and, therefore, no response is necessary. Should a response be deemed necessary, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

31. Defendants admit that the New Drug Application for Bextra® was filed with the FDA on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on November 16, 2001. Defendants deny any wrongful conduct and the remaining allegations in this paragraph of the Complaint.

32. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

33. Defendants state that the referenced FDA Talk Paper for Bextra® speaks for itself and respectfully refer the Court to the Talk Paper for its actual language and text. Any attempt to characterize the Talk Paper is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

34. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

35. Plaintiff fails to provide the proper context for the allegations concerning the "post-drug approval meta-analysis study" in this paragraph of the Complaint. Defendants are without sufficient information to confirm or deny such allegations, and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to

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the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

36. The allegations in this paragraph of the Complaint are not directed towards Defendants, and, therefore, no response is necessary. Should a response be deemed necessary, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

37. The allegations in this paragraph of the Complaint are not directed towards Defendants, and, therefore, no response is necessary. Should a response be deemed necessary, Defendants admit that a Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee was held on February 16-18, 2005. Defendants state that the referenced testimony speaks for itself and respectfully refer the Court to the testimony for its actual language and text. Any attempt to characterize the testimony is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

38. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

39. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language and text. Any attempt to characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

40. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language and text. Any attempt to characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

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41. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this paragraph of the Complaint.

42. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

43. The allegations in this paragraph of the Complaint are not directed towards Defendants, and, therefore, no response is necessary. Should a response be deemed necessary, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

44. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

45. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

46. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

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Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

47. Defendants deny the allegations in this paragraph of the Complaint.

48. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the allegations in this paragraph of the Complaint.

49. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with

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applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

50. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

51. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are therefore without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the allegations in this paragraph of the Complaint.

52. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are

by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

53. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

54. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

55. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

56. Defendants deny the allegations in this paragraph of the Complaint.

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57. Defendants admit that the sale of Bextra® was voluntarily suspended in the U.S. market as of April 7, 2005. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations contained in this paragraph of the Complaint.

58. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

59. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

60. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

61. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding and whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

62. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding and whether Plaintiff used

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Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

63. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

64. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding and whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

65. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are therefore without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

**Response to First Cause of Action: Negligence**

66. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

67. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

68. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

69. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

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Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

70. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

71. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

72. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

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73. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

74. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages and deny the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 74 of the Complaint, Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Second Cause of Action: Strict Liability**

75. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

76. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that Bextra® was expected to reach consumers without substantial change in the condition from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

77. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

78. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information,

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which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

79. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

80. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

81. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

82. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed

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by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

83. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

84. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

85. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

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86. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

87. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

88. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

89. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Third Cause of Action: Breach of Express Warranty**

90. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

91. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

92. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants

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state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint, including all subparts.

93. Defendants deny the allegations in this paragraph of the Complaint.

94. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

95. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct the remaining allegations in this paragraph of the Complaint.

96. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

97. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

98. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

99. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

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**Response to Fourth Cause of Action: Breach of Implied Warranty**

100. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

101. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

102. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

103. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

104. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

105. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

106. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

107. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was expected to reach consumers without substantial change in the condition from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

108. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

109. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

110. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

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111. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment**

112. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

113. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

114. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

115. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

116. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information,

which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

117. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

118. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

119. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

120. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

121. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

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122. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

123. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

124. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

125. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

126. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Sixth Cause of Action: Unjust Enrichment**

127. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

128. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

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129. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

130. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

131. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

132. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

133. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Prayer for Relief**

Answering the unnumbered paragraph of the Complaint headed "Prayer for Relief," Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

## III.
## GENERAL DENIAL

Defendants deny the allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not been previously admitted, denied, or explained.

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## IV.
## AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

**First Defense**

1. The Complaint fails to state a claim upon which relief can be granted.

**Second Defense**

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

**Third Defense**

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

**Fourth Defense**

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

**Fifth Defense**

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

**Sixth Defense**

6. Plaintiff's action is barred by the statute of repose.

**Seventh Defense**

7. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the negligence or fault of the Plaintiff and Plaintiff's damages, if any, are barred or reduced by the doctrines of comparative fault and contributory negligence and by the failure to mitigate damages.

**Eighth Defense**

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

**Ninth Defense**

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

**Tenth Defense**

10. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

**Eleventh Defense**

11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

**Twelfth Defense**

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff's treating and prescribing physicians.

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**Thirteenth Defense**

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

**Fourteenth Defense**

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

**Fifteenth Defense**

15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

**Sixteenth Defense**

16. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the unforeseeable alteration, change, improper handling, abnormal use, or other unforeseeable misuse of Bextra® by persons other than Defendants or persons acting on its behalf after the product left the control of Defendants.

**Seventeenth Defense**

17. Plaintiff's alleged damages were not caused by any failure to warn on the part of Defendants.

**Eighteenth Defense**

18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

**Nineteenth Defense**

19. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

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**Twentieth Defense**

20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*.

**Twenty-first Defense**

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

**Twenty-second Defense**

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

**Twenty-third Defense**

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

**Twenty-fourth Defense**

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

**Twenty-fifth Defense**

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

**Twenty-sixth Defense**

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

**Twenty-seventh Defense**

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

**Twenty-eighth Defense**

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

**Twenty-ninth Defense**

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

**Thirtieth Defense**

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution, Article I, § 17 of the Constitution of the States of Minnesota, and the Constitution of the State of Ohio, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

**Thirty-first Defense**

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of Minnesota and Ohio law, including, but not limited to, Minn. Stat. § 549.191 (2006).

**Thirty-second Defense**

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

**Thirty-third Defense**

33. Plaintiff's punitive damage claims are preempted by federal law.

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**Thirty-fourth Defense**

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

**Thirty-fifth Defense**

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

**Thirty-sixth Defense**

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

**Thirty-seventh Defense**

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

**Thirty-eighth Defense**

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitutions of the States of Minnesota and Ohio. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of

punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

**Thirty-ninth Defense**

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

**Fortieth Defense**

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

**Forty-first Defense**

41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

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**Forty-second Defense**

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

**Forty-third Defense**

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

**Forty-fourth Defense**

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

**Forty-fifth Defense**

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff.

**Forty-sixth Defense**

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

**Forty-seventh Defense**

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

**Forty-eighth Defense**

48. The claims must be dismissed because Plaintiff would have taken Bextra® even if the product labeling contained the information that Plaintiff contends should have been provided.

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**Forty-ninth Defense**

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

**Fiftieth Defense**

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

**Fifty-first Defense**

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

**Fifty-second Defense**

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

**Fifty-third Defense**

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug, & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

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**Fifty-fourth Defense**

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

**Fifty-fifth Defense**

55. Plaintiff's claims for punitive damages are barred, in whole or in part, by § 2315.21 of the Ohio Revised Code and are subject to all provisions of the Ohio Revised Code.

**Fifty-sixth Defense**

56. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources and the provisions of the Ohio Revised Code.

**Fifty-seventh Defense**

57. Plaintiff's fraud-based claims, if any, are not stated with particularity as required by Ohio law.

**Fifty-eighth Defense**

58. Plaintiff's damages, if any, must be reduced by the percentage of fault attributable to Plaintiff and to nonparties as provided by the Ohio Revised Code.

**Fifty-ninth Defense**

59. One or more of Plaintiff's claims for damages are subject to statutory limits on certain types of damages, and the Court is without jurisdiction to enter judgment for Plaintiff beyond the limits set forth in the Ohio Revised Code.

**Sixtieth Defense**

60. Ohio Senate Bill 120 and Senate Bill 80, now codified in various sections throughout the Ohio Revised Code, bar or limit one or more of Plaintiff's claims, including the limits and restrictions on damages set forth herein.

**Sixty-first Defense**

61. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

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## V.
## JURY DEMAND

Defendants hereby demand a trial by jury.

## VI.
## PRAYER

WHEREFORE, Defendants pray that Plaintiff takes nothing by this suit; that Defendants be discharged with their costs expended in this matter, and for such other and further relief to which Defendants may be justly entitled.

Dated: May 22, 2008.

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By_____/s/_____

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

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| IN RE BEXTRA AND CELEBREX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION | MDL Docket No. 1699 |
| *This document relates to* | CASE NO. 3:08-cv-02149-CRB |
| ALBERTA A. KREITZER, Plaintiff, vs. PFIZER, INC., PHARMACIA CORPORATION, G.D. SEARLE LLC and MONSANTO COMPANY, Defendants. | **RULE 7.1 STATEMENT**<br>**JURY TRIAL DEMANDED** |

Pursuant to Federal Rule of Civil Procedure 7.1, Defendants Pfizer Inc. ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC ("Searle") submit this their Corporate Disclosure Statement. Defendants Pfizer, Pharmacia and Searle state:

1. Defendant Pfizer Inc. does not have any parent corporations, and no publicly traded company owns 10% or more of Pfizer Inc.'s stock.

2. Defendant Pharmacia Corporation is a wholly-owned subsidiary of Defendant Pfizer Inc.

3. Defendant G.D. Searle LLC is a limited liability company whose sole member is Pharmacia & Upjohn Company LLC, which is a limited liability company whose sole member is Pharmacia & Upjohn LLC, which is a limited liability company whose sole member is Pharmacia Corporation.

May 22, 2008

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